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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/373,230	08/12/99	OKMURA	H OKAMURA=2E

001444 HM22/1222
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EXAMINER	
JIANG,D	
ART UNIT	**PAPER NUMBER**
1646	4

DATE MAILED: 12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/373,230	OKMURA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/502535* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED OFFICE ACTION

This application appears to be a division of Application No. 09/050,249, filed March 30, 1998. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

Claims 1-10 are pending and under consideration.

Formal Matters:

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the examiner is unable to find the term "a pharmacological composition" for the limitations of claims 2, 6 and 9 in the specification.

Additionally, the specification is objected to as using terminology, which is not generally accepted in the art and whose meaning cannot be determined. Specifically: "complementary amino acid sequences" (page 9, line 14).

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 7-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,912,324 by the same inventors. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the U.S. patent is directed to a purified protein which is the same protein as that in the claim 1 and 2 in the instant case and serves as "an effective ingredient" in "an INF-γ production inducing agent" or "a pharmacological composition" in the instant case. It is well known in the art "a purified protein" is usually used in combination with other agent(s) (such as dissolving solutions) rather than used as its crystal form alone. A combination of such in this case can be a purified IFN-γ production inducing protein (Claim 1 of U.S. Patent No. 5,912,324) and water (or buffer), which now becomes "An IFN-γ production inducing agent" (Claim 1 of the current application) without material change of the basic and novel characteristics of the claimed invention. It is, therefore, obvious that they are not patentably distinct from each other.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a specific variant of said protein, which has

an amino acid sequence of SEQ ID:2 where residue 70 is methionine or threonine, does not reasonably provide enablement for with claims to variants having "the amino acid sequence of SEQ ID:2 with one or more amino acid residues in SEQ ID:2 replaced with different amino acids or one or more amino acid residues deleted or added to the N-terminus of SEQ ID:2 while retaining the biological property", which, given the broadest interpretation, reads on any or all possible INF- γ inducing proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Enablement is not commensurate in scope with claims to any or all possible "variants" with INF- γ inducing activity. It is noted that the patentability of the claimed variants rests not on the biological property, but rather the particular sequences disclosed in the specification as filed because there exist other distinct proteins with the same biological property. As there is no upper limit given on the number of amino acid changes, the claims read on, therefore, any functionally equivalent protein with no structure similarity to SEQ ID:2 actually required. Additionally, there is a lack of predictability in the prior art on the relationship of the function and structure of the INF- γ inducing proteins because of the lack of sequence identity, and the specification of the current application discloses only two distinct species of the INF- γ inducing protein with single amino acid substitution, it does not provide clear direction or enough guidance to teach how to make a commensurate number of the claimed species without altering the biological property. Based upon the very limited number of disclosed species, it is not at all predictable what essential structures are required for the protein to be functional, and it would require undue experimentation to determine such. As the specification does not teach how to

make a number of species that would be commensurate in scope with the claim, it is found that it would require undue experimentation to practice the invention in a manner commensurate in scope with the claim, given the lack of guidance in the specification and the very broad scope of the claim. Further, there is no working example to support the current claims. Given the breath of claims 3-6 in light of the predictability of the art, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make the claimed invention in a manner commensurate in scope with the claims.

The Examiner notes that the description of claimed proteins via a biological function (in this case that of INF-γ inducing activity) is similar to the situation in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) in which it was found that:

> Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

In the current instance, the claims do not positively identify the protein of the invention by its sequence, but rather define such in terms of its biological activity. Therefore, the currently pending claims are analogous to the DNA claims in *Maizel*, in which the DNA was defined by the biological activity of the protein it encoded.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8 are indefinite because it is not clear whether "a ... agent" is a compound or a composition. Said term could read on a composition as the open language "contains" is used. However, there is no additional compound mentioned in the claims. Further, if said term reads on a compound, it is confusing when the open language "contains" follows. The claims, therefore, are indefinite.

Claims 3-5 are indefinite because it is not clear what a "variant" is. There is no limiting definition of the term "variant" in the specification. The metes and bounds of the "variant" in the claims are vague due to the use of a relative term "one or more". The term "more" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case it is not clear as how many is "more". Given the broadest interpretation, reads on an indefinite number of amino acid residues being replaced, deleted or added while retaining the biological property, up to and including replacement of the entire protein. Claim 4 is further vague and indefinite because "has one" amino acid residue replaced might indicate "has only one" or alternatively "has at least one".

Claim 10 is indefinite because it is not clear what "homologous" is, and the specification does not provide what is intended by "homologous". The metes and bounds of the claim, therefore, cannot be unambiguously determined. The claim is further indefinite because the terms "small number of" and "substantially altering" the biological properties in are relative terms which render the claim indefinite. The term "small number of" and "substantially altering" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how many are "small number of" and how much change in biological properties is "substantially altering".

Claim 6 is rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993; provided by the applicant). Nakamura et al. disclose a purified protein factor (abstract) which migrates at 50-55 kDa on SDS-PAGE (page 68, col. 2, second paragraph). Compositions comprising this factor and various other substances in PBS (page 65, paragraph bridging columns) induce the production of IFN-γ in resting T and NK cells (abstract).

Claims 3 and 5-6 of the current invention, given the broadest interpretation, read on any or all possible INF- γ inducing proteins with INF- γ inducing activity as said protein is defined by its biological property, rather the particular sequence disclosed in the specification. Such broad claims include other species of proteins with the same said function, but different structural features, such as the protein factor anticipated by Nakamura et al.. Because the characteristic biological property of the protein factor is identified in the prior art, the prior art protein inherently meets the limitations of the claims 3 and 5-6 in the instant case.

Conclusion:

No claim is allowable.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

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